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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/023,483      | 02/13/1998  | JEFFREY A. HEROUX    | 2528-2              | 6994             |

7590 11/16/2001

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8TH FLOOR  
ARLINGTON, VA 22201

EXAMINER

TUNG, JOYCE

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1656

DATE MAILED: 11/16/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.  
**09/023,483**

Applicant(s)  
**Heroux et al.**

Examiner  
**Joyce Tung**

Art Unit  
**1656**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Aug 26, 2001.
- 2a) ☒ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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***Response to Amendment***

1. The amendment filed 8/26/2001 has been entered.
2. The rejection of claims 1-40 under 35 U.S.C. 112, second paragraph is withdrawn because of the amendment and argument.
3. Regarding the rejections of claims 1-3, 6-12, 14-25, 28-32 and 34-37 over Hartley in view of Eberle et al., the response argues that the cited art does not teach or suggest the fundamental aspects of the presently claimed invention or motivation to make the presently claimed invention in which the total nucleic acid is measured in a sample and amplified with at least one random primer, specifically, Hartley describes the detection of the presence of the pathogens in a sample. However, Hartley also indicates that amplification of a human tissue sample infected with a virus may result in amplification of both viral and human sequences (See column 3, lines 18-21). This suggests that the total DNA is amplified. The method of Hartley also might be desirable in the quantification of the amplification product in which primers are labeled with biotin (See column 6, lines 39-43) and capture beads are used (See column 12, lines 10-14). The response further argues that the method of Hartley uses the specific probes for measuring and detecting specific sequences. Nevertheless, the claim language indicates that the amplification mixture contacts at least one solid phase and the total amount of said at least one detectable species bound to the solid phase is measured. This indicates that there is a probe attached to the solid phase, even though there is no word "probe".

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In addition, The response argues that Eberle et al. do not disclose measuring the total nucleic acid in a sample. As indicate in the Office action mailed 2/28/2001 that the promoter sequence used in the method of Eberle et al. is a nucleic acid sequence, this indicates that the method of Eberle et al. will be used for detecting a nucleic acid sequence and the detecting step is needed for quantification, Thus, since the claim language "total nucleic acid in a sample" is not clearly defined, an ordinary skill in the art would have been motivated to combine the teachings of Hartley and Eberle et al. to make the instant invention as claimed. Therefore, the rejection is maintained.

4. Claims 1-3, 6-12, 14-25, 28-32 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley (5,043,272) in view of Eberle et al. (5,413,906).

5. Regarding the rejection of claims 4, 5, 13, 26, 27, 33 and 39-40 over Hartley in view of Wu et al. and Respess and the rejection of claims 38 over Hartley in view of Kozlowski et al., since these claims depend from the claims which are rejected over Hartley in view of Eberle et al., with the same reasons set forth in section 3 above, the rejection is maintained.

6. Claims 4, 5, 13, 26, 27, 33 and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley (5,043,272) in view of Wu et al. (Genomics, 1989, vol. 4, pg. 560-569) and Respess (5,599,662).

7. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley (5,043,272) in view of Kozlowski et al. (6,096,499).

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8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached at (703) 308-1152.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1656 via the PTO Fax Center located in Crystal

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Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

November 7, 2001

A handwritten signature in black ink, appearing to read "E Campbell". The signature is written in a cursive, flowing style.

**EGGERTON A. CAMPBELL  
PRIMARY EXAMINER**